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**ENVIRONMENTAL PROTECTION AGENCY**

**[EPA-HQ-OPP-2016-0093; FRL-10017-83]**

# Pesticides; Final Guidance for Waiving Acute Dermal Toxicity Tests for Pesticide Technical Chemicals and Supporting Retrospective Analysis; Notice of Availability

**AGENCY**: Environmental Protection Agency (EPA).

**ACTION**: Notice.

**SUMMARY**: The Environmental Protection Agency (EPA) is announcing the availability of the final guidance document entitled "Guidance for Waiving Acute Dermal Toxicity Tests for Pesticide Technical Chemicals & Supporting Retrospective Analysis." Guidance documents are issued by the Office of Pesticide Programs (OPP) to inform pesticide registrants and other interested persons about important policies, procedures, and registration related decisions, and serve to provide guidance to pesticide registrants and OPP personnel. This final guidance document provides information to pesticide registrants concerning the Agency's decision to expand the potential for data waivers for acute dermal studies to single technical active ingredients (technical AIs) used to formulate end use products.

**FOR FURTHER INFORMATION CONTACT**: Tara Flint, Antimicrobial Division (7510P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 347-0398; email address: *flint.tara@epa.gov*.

**SUPPLEMENTARY INFORMATION:**

## I. Does this action apply to me?

This action is directed to the public in general. Although this action may be of particular interest to those persons who are or may be required to conduct testing of chemical substances under the Federal Food, Drug, and Cosmetic Act (FFDCA), or the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Since other entities may also be interested, the Agency

has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

## II. What action is the Agency taking?

### *A. Authority*

This guidance is provided under the authority of FIFRA (7 U.S.C. 136 *et seq*.) and addresses the utility of the acute dermal toxicity study for single technical chemicals in pesticide labelling, such as the signal word and precautionary statements as described in 40 CFR 156.64 and 40 CFR 156.70.

### *B. Background*

EPA's OPP regularly receives acute lethality studies for oral, dermal and inhalation routes along with eye irritation, skin irritation, and skin sensitization – these data are required for both the registration of new and reregistration of existing pesticidal products.

In 2016, OPP published the "*Guidance for Waiving Acute Dermal Toxicity Tests for Pesticide Formulations & Supporting Retrospective Analysis*" to support the Agency's goal to reduce unnecessary animal testing. The retrospective analysis supports the conclusion that the dermal acute toxicity study for formulations provides little to no added value in regulatory decision making.

In 2017 Canada's Pest Management Regulatory Agency (PMRA) released their *Acute Dermal Toxicity Waiver*. This policy includes both end use products and technical active ingredients. Stakeholders have requested that EPA expand its waiver guidance for technical active ingredients to support North American harmonization.

In 2019 EPA Administrator Wheeler directed Agency leadership to prioritize animal testing reduction efforts.

In 2020, the Agency published the draft guidance for public comment on October 8, 2020 (85 FR 63548), and received supportive comments from stakeholders. Therefore, the Agency is

finalizing the draft guidance as proposed.

This final guidance document expands the potential for data waivers for acute dermal studies to single active ingredient technical chemicals (technical chemicals) used to formulate end use products. The reasoning and analysis in this dermal waiver guidance for technical chemicals is similar to what was presented in the 2016 guidance for end-use products. While more acute toxicity studies are submitted to OPP annually for formulated pesticide products than for technical chemicals, there is still the potential for animal and resource savings from waivers for technical chemical acute toxicity studies. Further, this guidance will allow EPA to harmonize with the PMRA.

**III. Do guidance documents contain binding requirements?**

As guidance, this document is not binding on the Agency or any outside parties, and the Agency may depart from it where circumstances warrant and without prior notice. While EPA has made every effort to ensure the accuracy of the discussion in the guidance, the obligations of EPA and the regulated community are determined by statutes, regulations, or other legally binding documents. In the event of a conflict between the discussion in the guidance document and any statute, regulation, or other legally binding document, the guidance document will not be controlling.

**IV. Statutory and Executive Order Reviews**

Additional information about these statutes and Executive Orders can be found at https://www.epa.gov/laws-regulations/laws-and-executive-orders. This unit addresses those requirements that apply to a guidance document.

*A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review*

The Office of Management and Budget (OMB) determined that this is not a significant regulatory action under Executive Order 12866 (58 FR 51735, October 4, 1993). The guidance was not, therefore, submitted to OMB for review under Executive Orders 12866 and 13563 (76

FR 3821, January 21, 2011).

*B. Paperwork Reduction Act (PRA)*

This guidance document does not create any new information collection burden that require additional approval by OMB under the PRA, 44 U.S.C. 3501 *et seq*. Burden is defined in 5 CFR 1320.3(b). The information collection activities associated with pesticide registration are already approved by OMB under OMB Control No. 2070-0060.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information that requires OMB approval under the PRA, unless it has been approved by OMB and displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in Title 40 of the CFR, after appearing in the **Federal Register**, are listed in 40 CFR, part 9, and included on the related collection instrument, or form, as applicable.

**Authority**: 7 U.S.C. 136 *et seq*.

Dated: March 10, 2021.

**Michal Freedhoff,**

*Acting Assistant Administrator, Office of Chemical Safety and Pollution Prevention.*

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